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April 24, 2013

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004



Subject: Notice in Accordance with TSCA Section 8(e): Results of a repeated-dose toxicity study in C57BL/6 J Rj mice with an experimental pesticide

Dear Section 8(e) Coordinator:

[REDACTED] is submitting the results of a repeated-dose toxicity study in C57BL/6 J Rj mice with [REDACTED] conducted by [REDACTED]. The test substance is an experimental pesticide

The aim of this study was to obtain information on the effect of the test substance to C57BL/6 J Rj mice after repeated oral administration via the diet before the beginning of subsequent repeated-dose studies.

The test substance was administered to groups of 4 male and 4 female C57BL/6 J Rj mice for 14 days. The nominal dose levels were 0, 2000 and 5000 ppm.

The following is a summary of the most relevant results:

5000 ppm:

- Poor general condition in all female animals
- Body weight loss in both gender between study days 0 and 3, i.e. body weights were reduced by -14% in males and -17% in females compared to control animals. Lower mean body weight values at the end of the study period in both gender.
- Reduced terminal body weights in male (-11%) and female animals (-8%)
- Increased absolute liver weights, i.e. +60% in males and +78% in females
- Increased relative liver weights, i.e. +81% in males and +92% in females
- Decreased absolute weights of the kidney, i.e. -9% in males
- Enlarged livers in 2 male and 2 female animals
- Centrilobular hypertrophy in livers of all male and diffuse hypertrophy in all female animals
- Bile duct hyperplasia in all male and all female animals
- Multifocal necrosis in livers of all male and 3 female animals
- Lymphoid infiltration in livers of all male and all female animals
- Oval cell proliferation in livers of all male and all female animals



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2000 ppm:

- Increased absolute liver weights, i.e. +28% in males and +33% in females
- Increased relative liver weights, i.e. +34% in males and +37% in females
- Centrilobular hypertrophy in livers of all male and diffuse hypertrophy in all female animals
- Bile duct hyperplasia in 2 male and 2 female animals
- Multifocal necrosis in livers of 3 male and 1 female animals
- Lymphoid infiltration in livers of 1 male and all female animals
- Oval cell proliferation in livers of 2 male and 2 female animals

[REDACTED] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures

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